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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,836	11/08/2006	Lars Ole Lyngso	05432/1200888-US1	6949
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770				
			EXAMINER	
			GALLIS, DAVID E	
			ART UNIT	PAPER NUMBER
			1625	
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			03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,836	<b>Applicant(s)</b> LYNGSO, LARS OLE
	<b>Examiner</b> DAVID E. GALLIS	<b>Art Unit</b> 1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 November 2006.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/27/06</u> | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 1 through 40 are pending. Claims 1, 2, 3, 4, 7, 10 through 20, 22 through 26, and 30 through 31 have been amended. Claims 33 through 40 have been newly added. Applicant's claim to priority from provisional application 60/544970 filed February 12, 2004 is acknowledged.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 10, 11, 13, 15 through 21, and 23 through 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some formula I and IV structures and substituents, separation techniques, and conversion sequences, does not reasonably provide enablement for all formula I and IV structures and substituents applied to claimed methods, all separation techniques, all conversion sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

4. Claim 1 is not enabling for the use of all cyclic anhydride and imide structures of formula I. Clearly the only working example entails the use of succinic anhydride in tetrahydrofuran. The isolation and purification method depends on the differential solubilities of structures IV and V generated with anhydrides of structure I. However, there is no information offered within the specification regarding the ability of such

varied structures V to precipitate from tetrahydrofuran, nor is any information available regarding alternative solvents and how they may or may not facilitate the formation of structure V. Therefore, the only enabled anhydrides for claims 1, 16 through 21 are those of structures Ia and Ib where n=0, both Q<sup>1</sup> and Q<sup>2</sup> are carbon, and R', R'' and R''' are hydrogen and alkyl. Furthermore, compounds of formula IV are not enabled for all optional R, R<sup>1</sup>, Y and Z substituents in claims 1, 13, 15 and 23 through 27. This structure is not enabling where R is not cyano, Y is not equal to a bond, Z is not dimethylamino, where R<sup>1</sup> comprises alkylthio and hydroxyl functional groups, and where the dotted line represents a double bond. Such R<sup>1</sup> groups would have the same magnitude of reactivity toward the enabled anhydrides as would the hydroxyl of the diol of structure II, thereby defeating the isolation and purification method. Furthermore, R substituents such as OH, CH<sub>2</sub>OH, and CH<sub>2</sub>NH<sub>2</sub> for example, and Z substituents such as MgHal for example are all reactive groups in the context of the isolation and purification procedure. In fact, Applicant makes a point of protecting the generic hydroxyl and amino Z group alternatives in the specification (see page 23 lines 12 through 32). Additionally, claim 1 is not enabling for all separation techniques for compounds of formulas IV and V. The only working example for such a separation is that of a precipitation of crystalline compound of formula V. The polarity of free functional groups greatly effect the absorption/desorbtion properties of both structures IV and V. The specification does not offer any insight regarding the interaction of acidic and protic structure IV R and Z moieties with a basic resin. This is likewise true for biphasic liquid extraction. The specification does not offer any insight regarding the

effects of polar and non-polar structure IV R and Z moieties toward differential solubilities of structures IV and V in organic and aqueous media. Claims 10 and 11 are not enabling for the conversions of R, Hal, and Z groups in any order. As per the working example, R, Hal, and Z are respectively cyano, fluorine, and dimethylaminomethyl prior to the use of the methods of claim 4 and 7. As discussed above, convertible R substituents such as OH, CH<sub>2</sub>OH, and CH<sub>2</sub>NH<sub>2</sub> for example, and convertible Z substituents such as MgHal for example are all reactive groups in the context of the isolation and purification procedure. Furthermore, Applicants state that these functional group conversions are preferentially and suitably "carried out after ring closure to form a compound of formula (V)" (see page 23 line 5, and page 25, line 13). Therefore, claims 10 and 11 are not enabled for any order of R, Hal, and Z conversion following the use of the method according to claims 4 and 7.

5. "The factors to be considered [in making an enablement rejection] have been summarized as a) the quantity of experimentation necessary, b) the amount of direction or guidance presented, c) the presence or absence of working examples, d) the nature of the invention, e) the state of the prior art, f) the relative skill of those in that art, g) the predictability or unpredictability of the art, h) and the breadth of the claims, *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.  
a) Determining formula I and IV structure and substituent viability, the applicability of optional separation techniques and conversion sequences would require extensive experimentation. The extensive listing of optional functional groups lends to very diverse and/or unknown solubilities and reactivities. Clearly the claimed isolation

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technique is predicated on the existence of a free and reactive hydroxyl group that is unavailable in compound IV. The optional R<sup>1</sup> substituents such as hydroxyl offer such functionality that would defeat the method itself. Likewise, the workable parameters of liquid extraction and resin adsorption/desorption, and the affects of convertible fictional groups are not disclosed. b) The direction concerning the claimed method of isolation and purification is found in the disclosure on page 27 as Example 1. The balance of the specification relates to enzymatic acylation/deacylation and functional group conversion. c) There are no working examples for alternative separation techniques or alternative synthetic sequences incorporating the claimed isolation and purification method. d) The nature of the invention is separation science. e) The state of the chemical art currently lacks knowledge of how to simply apply a single isolation/purification procedure to such a diverse set of formula V and IV structures. f) Artisans using Applicant's invention would require a Ph.D. degree, and several years of practical research experience. g) It is well established that the scope of enablement varies inversely with the degree of unpredictability of the factors involved, and the application of such varied structures to a single isolation and purification method would generally be considered an unpredictable factor. h) The breadth of the claims includes processes requiring procedural and synthetic descriptions not available in the disclosure.

6. Claims 2 through 9, 12, 14, 22, and 28 through 40 are rejected due to their dependency on rejected claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L ANDRES/  
Supervisory Patent Examiner, Art Unit 1625

David E. Gallis  
Patent Examiner